

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: RU-0223

Inventors: Minko et al.

Serial No.: 10/780,137

Filing Date: February 17, 2004

Examiner: Not Yet Assigned

Group Art Unit: 1642

Title: Complex Drug Delivery Composition and

Method for Treating Cancer

I, Jane Massey Licata, Registration No. 32,257, certify that this correspondence is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to the Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450

On this date: April 19, 2004

Jane Massey Licata, Registration No. 32,257

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

(XX) In accordance with §1.97(b), since this Information

Disclosure Statement is being filed either within three

months of the filing date of the above-identified

application, within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, no additional fee is required.

- () In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, therefore:
 - () Certification in Accordance with §1.97(e) is attached hereto; or
 - () Authorization to charge Deposit Account No. 50-1616 the fee of \$180.00 as set forth in §1.17(p) is provided.
- () In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee, therefore included are: Certification in Accordance with §1.97(e); Petition Requesting Consideration of the Information Disclosure Statement; and the fee of \$130.00 as set forth in §1.17(I)(1).
- (XX) Copies of each of the references listed on the attached Form PTO-1449 (modified) are enclosed herewith.

() In accordance with §1.98(d), copies of some or all of the references listed on the attached Form PTO-1449 (modified) are not enclosed herewith because they were previously submitted to the U.S. Patent and Trademark Office in prior application Serial No. ______, filed _______, for which a claim for priority under 35 U.S.C. §120 has been made in the instant application.

Please charge any deficiency or credit any overpayment to Deposit Account No. 50-1619. This form is submitted in duplicate.

- () The relevance of the listed references in a foreign language is as stated in the specification at pages @@.
- (XX) All listed references are in the English language.

Respectfully submitted,

Javassfrede

Jane Massey Licata Registration No. 32,257

Date: <u>April 19, 2004</u>

Licata & Tyrrell P.C. 66 E. Main Street Marlton, New Jersey 08053

(856) 810-1515

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Form PTO-1449 Modified		Docket No. RU-0223	Serial No. 10/780,137		
List of Patents and Publications Cited by Applicant (Use several sheets if necessary)		Applicant Minko et al.			
U.S. Department of Commerce		Filing Date February 17, 2004	Group 1642		
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)					
	DiPaola et al., "Targeting Apoptosis in Prostate Cancer", Hematol. Oncol. Clin. North Am. 2001 15:509-524				
Activity of a C	Conover et al., "Camptothecin Delivery Systems:The Antitumor Activity of a Camptothecin-20-0-Polyetheylene Glycol Ester Transport Form", Anticancer Res. 1997 17:3361-3368				
conjugates:des	Kopecek et al., "HPMA copolymer-anticancer drug conjugates:design, activity, and mechanism of action", Eur. J. Pharm. Biopharm 2000 50:61-81				
	Kopecek et al., "Water soluble polymers in tumor targeted delivery", J. Controlled Rel. 2001 74:147-158				
seminal ribonucle	Michaelis et al., "Coupling of the antitumoral enzyme bovine seminal ribonuclease to polyethylene glycol chains increases its systemic efficacy in mice"Anticancer Drugs 2002 13:149-154				
HPMA Copolymer-	Minko et al., "Efficacy of the Chemotherapeutic Action of HPMA Copolymer-Bound in Doxrubicin in a Solid Tumor Model of Ovarian Carcinoma", Int. J. Cancer 2000 86:108-117				
MDR1 gene enco	Minko et al., "HPMA copolymer bound adriamycin overcomes MDR1 gene encoded resistance in a human ovarian carcinoma cell line", J. Controlled Rel. 1998 54:223-233				
does not induce t	Minko et al., "Chronic exposure to HPMA copolymer-bound adriamycin does not induce multidrug resistance in a human ovarian carcinoma cell lines", J. Controlled Rel. 1999 59:133-148				
Gene Modulated Vas	Minko et al., "The Influence Cytotoxicity of Macromolecules and of VEGF Gene Modulated Vascular Permeability on the Enhanced Permeability and Retention Effect in Resistant Solid Tumors", Pharm. Res. 2000 17:505-514				
EXAMINER		DATE CONSIDERED			

Sheet 02 of 03

Form PTO-1449 Modified List of Patents and Publications Cited by Applicant (Use several sheets if necessary)		Docket No. RU-0223	Serial No. 10/780,137			
		Applicant Minko et al.				
U.S. Department of Commerce		Filing Date February 17, 2004	Group 1642			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)						
	AJ	Minko et al., "Enhancing the anticancer efficacy of camptothecin using biotinylated poly(ethyleneglycol) conjugates in sensitive and multidrug-resistant human ovarian carcinoma cells", Cancer Chemother Pharmacol. 2002 50:143-150				
	AK	Minko et al., "Comparison of the Anticancer Effect of Free and HPMA Copolymer-Bound Adriamycin in Human Ovarian Carcinoma Cells", Pharm. Res. 1999 16(7):986-996				
	AL	Minko et al., "Preliminary evaluation of caspases-dependent apoptosis signaling pathways of free and HPMA copolymer-bound doxorubicin in human ovarian carcinoma cells", J. Control. Rel. 2001 71:227-237				
	AM	Minko et al., "Advanced Drug Delivery Systems in Cancer Chemotherapy", Disease Management and Clinical Outcomes 2001 3:48-54				
EXAMINER		1-3,	DATE CONSIDERED			

Sheet 03 of 03 Docket No. Serial No. Form PTO-1449 Modified 10/780,137 RU-0223 List of Patents and Publications Cited by Applicant Applicant (Use several sheets if necessary) Minko et al. U.S. Department of Commerce Filing Date Group February 17, 2004 1642 U. S. PATENT DOCUMENTS Examiner Document Date Name Class Subclass Initial No. BA 6,258,774 7-10-01 Stein et al. 514 2 FOREIGN PATENT DOCUMENTS Examiner Document No. Translation Date Country YES NO Initial BBWO 97/19954 5-6-97 PCT EXAMINER DATE CONSIDERED